WO 2005/017208 PCT/US2004/002064

CLAIMS

- 1. A method of preventing HIV infection in a subject in need thereof, comprising: administering an effective amount of a vaccinia virus, wherein said amount is effective to prevent HIV infection, with the proviso that HIV nucleic acid is not contained within the vaccinia virus genome.
- 2. A method of preventing HIV infection in a subject in need thereof, comprising: administering through the mucosa an effective amount of a vaccinia virus, wherein said amount is effective to prevent HIV infection.

10

5

- 3. A method of claim 2, with the proviso that HIV nucleic acid is not contained within the vaccinia virus genome.
- 4. A method of preventing HIV infection in a subject in need thereof, comprising:
 administering an effective amount of an attenuated vaccinia virus, wherein said amount is effective to prevent HIV infection.
 - 5. A method of claim 4, wherein said attenuated vaccinia virus is MVA (ATCC No. VR-1508), MVA-BN (ECACC No. V00083008), MVA 572 (ECACC V94012707), or ACAM1000 (ATCC No. PTA-3321).
 - 6. A method of claim 1, wherein said subject has been exposed to HIV virus or is at risk for exposure to HIV.
- 7. A method of claim 1, further comprising administering a second effective amount of a vaccinia at a predetermined time interval following the administering of the first amount.
 - 8. A method of claim 1, wherein said vaccinia virus is an attenuated vaccinia virus.

30

20

9. A method of claim 1, wherein said poxvirus is administered through the mucosa.

WO 2005/017208 PCT/US2004/002064 -55-

- 10. A method of claim 1, wherein said vaccinia virus utilizes a CCR5 chemokine receptor for entry into a cell.
- 11. A method of claim 1, further comprising monitoring the HIV status of said5 subject.
 - 12. A method of claim 1, where said poxvirus has been assayed for its ability to interfere with HIV infection.
- 13. A method of claim 1, wherein the preventing HIV infection is not a result of an immunological response to a poxvirus antigen.
- 14. A method of preventing HIV infection in a subject in need thereof, comprising:
 administering an effective amount of a vaccinia virus component, wherein said
 amount is effective to prevent HIV infection.
 - 15. A method of claim 14, wherein said component is a polypeptide coded for by vaccinia virus.
- 20 16. A method of claim 14, wherein said component is a vaccinia virus nucleic acid.
 - 17. A method of preventing HIV infection in a subject in need thereof, comprising administering multiple doses of a vaccinia virus, or a component thereof, to a subject, wherein each dose is administered at a predetermined time interval from the previous dose, and are effective to maintain protection against HIV infection.
 - 18. A method of claim 17, wherein said time interval is at least one month.

25

19. A method of claim 17, with the proviso that HIV nucleic acid is not contained30 within the vaccinia virus genome.

20. A method of treating HIV infection in a subject in need thereof, comprising: administering an effective amount of a vaccinia virus, or a component thereof, to a subject infected with HIV, wherein said amount is effective to treat HIV infection.

5

15

20

- 21. A method of claim 20, whereby the progression of the HIV infection is delayed in said subject.
- 22. A method of treating HIV infection in a subject in need thereof, comprising:

 administering an effective amount of an attenuated vaccinia virus to a subject infected with HIV, wherein said amount is effective to treat HIV infection.
 - 23. A method of treating HIV infection in a subject in need thereof, comprising: administering an effective amount of a vaccinia virus component to a subject infected with HIV, wherein said amount is effective to treat HIV infection.
 - 24. A method of treating HIV infection in a subject in need thereof, comprising: administering multiple doses, each having an effective amount of an attenuated vaccinia virus to a subject infected with HIV, wherein said amount is effective to treat HIV infection and wherein each dose is administered at a predetermined time interval from the previous dose, and are effective to maintain protection against HIV infection
- 25. A method of identifying a poxvirus, or a component thereof, which confers
 resistance on an organism to HIV infection, comprising:

administering poxvirus, or a component thereof, to an organism which is susceptible to HIV infection, or to cells derived from said organism,

contacting said organism, or cells derived from said organism, with HIV under conditions effective for said HIV to infect said cell or organism, and,

identifying the poxvirus, or component thereof, which confers resistance to HIV infection.

WO 2005/017208 PCT/US2004/002064 -57-

- 26. A method of claim 25, with the proviso that HIV nucleic acid is not contained with the poxvirus genome.
- 27. A method of identifying a vaccinia virus, or a component thereof, which confers resistance on an organism to HIV infection, comprising:

5

15

25

administering vaccinia virus, or a component thereof, to an organism which is susceptible to HIV infection, or to cells derived from said organism,

contacting said organism, or cells derived from said organism, with HIV under conditions effective for said HIV to infect said cell or organism, and,

- identifying the vaccinia virus, or component thereof, which confers resistance to HIV infection.
 - 28. A method of claim 27, with the proviso that HIV nucleic acid is not contained with the poxvirus genome.
 - 29. A method of 27, wherein said identifying comprises

 detecting the expression in said cells of gp120, HIV reverse transcriptase, p24, infectious HIV particles and/or HIV nucleic acid.
- 20 30. A method of 27, with the proviso that said method does not comprise administering HIV nucleic acid.
 - 31. A method of claim 27, consisting of administering said vaccinia virus, or a component thereof.

WO 2005/017208

PCT/US2004/002064

-58-

32. A method of identifying a vaccinia virus-associated agent which interferes with HIV infection, comprising

contacting a mammalian cell or mammalian organism susceptible to HIV infection with a vaccinia virus-associated agent which is produced by a cell or organism after exposure to vaccinia virus, and

contacting said cell or organism with HIV under conditions effective for said HIV to infect said cell or organism, and,

determining that said cell or organism is resistant to HIV infection, whereby said agent is identified as interfering with HIV infection.

10

5

33. A composition for treating and/or preventing HIV infection, comprising a soluble extract which is produced by a mammalian cell or mammalian organism after exposure to vaccinia virus, with the proviso that said extract does not comprise vaccinia immunoglobulin.

15

30

- 34. A composition of 33, which is an extract of blood serum obtained from an organism which has been exposed to vaccinia virus.
- 35. A composition of 33, which is a culture medium in which said cells exposed to vaccinia virus were grown.
 - 36. A kit for preventing HIV infection, comprising:

an effective amount of a poxvirus, and

instructions for administering an effective amount of said poxvirus to a subject

- 25 to prevent HIV infection.
 - 37. A kit for preventing HIV infection, comprising:

an effective amount of a vaccinia virus, and

instructions for administering an effective amount of said vaccinia virus to a subject to prevent HIV infection.

38. A kit for treating HIV infection, comprising:

an effective amount of a poxvirus, and

instructions for administering an effective amount of said poxvirus to a subject to treat HIV infection.

5

39. A kit for treating HIV infection, comprising:

an effective amount of a vaccinia virus, and

instructions for administering an effective amount of said vaccinia virus to a subject to treat HIV infection.

10

40. A combination for treating HIV, comprising:

an effective amount of vaccinia virus, or a component thereof, or a vaccinia immunoglobulin, and

an effective amount of an agent for treating HIV infection.

15

- 41. A combination of 40, wherein said agent for treating HIV infection is an HIV protease inhibitor, an HIV reverse transcriptase inhibitor, or a CCR5 antagonist.
- 42. A method of making a vaccinia virus composition for conferring resistance to HIV infection, comprising:

preparing a composition comprising vaccinia virus, or a vaccinia virus component thereof, and

determining that said composition confers resistance to HIV infection to an organism or cell challenged with it.

25

30

43. A method of claim 42, wherein said determining whether said composition confers resistance to HIV infection is accomplished by:

challenging said organism, or cell, with infectious HIV, and detecting the expression in said organism or cells of gp120, HIV reverse transcriptase, p24, infectious HIV particles, and/or HIV nucleic acid.

44. A method of making a vaccinia virus composition for conferring resistance to HIV infection, comprising:

preparing a composition comprising vaccinia virus, or a vaccinia virus component thereof, and

- identifying that said composition confers resistance to HIV infection to an organism challenged with it.
 - 45. A method of claim 44, wherein said identifying is determining that said composition confers resistance to HIV infection by:
- 10 challenging said organism, or cells derived from it, with infectious HIV, and detecting the expression in said organism or cells of gp120, HIV reverse transcriptase, p24, infectious HIV particles, and/or HIV nucleic acid.
- 46. A method of advertising the sale of a poxvirus for preventing or treating HIV infection, comprising:

displaying information about a poxvirus for preventing or treating HIV infection.

- 47. A method of claim 46, wherein said information is displayed on a computer 20 screen.
 - 48. A method of claim 46, wherein said information is stored in computer-readable form.

5